OMB

Display Date 9-30-99
Publication Date 10-1-99
Certifier SNReese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1651]

Guidance for Industry: Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA.'' This draft guidance is intended to provide recommendations to holders of new animal drug applications (NADA's) and abbreviated new animal drug applications (ANADA's) on how they should report changes to such applications in accordance with proposed amended regulations that are found elsewhere in this issue of the **Federal Register**.

DATES: Written comments should be submitted by (*insert date 75 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Office of New Animal Drug Evaluation (HFV–140), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

I. Background

Section 116 of the Food and Drug Administration Modernization Act (the Modernization Act) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a). This section provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such change. Elsewhere in this issue of the **Federal Register**, FDA is proposing to amend its regulations on supplements and other changes to an approved application § 514.8 (21 CFR 514.8) to conform to section 506A of the act.

The purpose of this draft guidance is to provide recommendations to holders of NADA's and ANADA's who intend to make postapproval changes in accordance with section 506A of the act and the proposed amended regulations at § 514.8. The draft guidance covers recommended reporting categories for postapproval changes for new animal drugs. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, and (6) miscellaneous changes. This draft guidance does not provide recommendations on the specific information that should be developed by an applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product. FDA has published guidances, including the Scale-up and Postapproval Changes (SUPAC) guidances, that provide recommendations on reporting categories and/or the type of information that should be developed by the applicant to validate the effect of the change on the identity, strength, quality, purity, or potency of a product

as they may relate to the safety or effectiveness of the product. The draft guidance, which cites proposed § 514.8, will be revised based on public comments and implemented for use as a companion document when § 514.8 is finalized.

This draft guidance represents the agency's current thinking on this subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

II. Comment

Interested persons may, on or before (*insert date 75 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

Dated: 6-23-99

June 23, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Suzette N. Reese